EndoChoice, Inc.,
11810 Wills Road
Alpharetta, GA 30009

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92

Submitter Details

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OCT 10 2013

Date prepared: June 18, 2013

Submission Contact: Tamar Fuerst EndoChoice Innovation Center Ltd. Caesarea, 38900, Israel. Phone: +972-46327731, Fax: +972-46327743

Device Details

Proprietary Name:	PeerScope System (Model HG)
Classification Name	Endoscope and Accessories, 21 CFR 876.1500
Product Code:	FDS
Committee/Panel:	Gastroenterology/Urology
Device Class:	II

Reason for 510(k) Submission: New Device

Identification of Legally Marketed Predicates Devices:

EVIS EXERA II 180 System (K100584) by Olympus.
PeerScope System Model H (K130718) - by PeerMedical Ltd.

Device Description

The PeerScope System Model HG is a GI platform for diagnostic visualization and therapeutic intervention of the digestive tract for use in healthcare facility/hospital. The system consists of the Main Control Unit (MCU) Videoprocessor that provides the device controls, user interfaces, image processing, pneumatic controls and interfaces with various external accessories, and of the PeerScope GS flexible video Gastroscope labeled for repeatable clinical usage within the upper digestive tract. The operation principles of the PeerScope System are similar to those of other legally marketed standard Gastroscopic systems. The system also provides the physicians with two viewing capabilities: Standard 160° front field of view, and 210° wide field of view.

Intended use and indications for Use

The PeerScope System is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The PeerScope System is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).
The PeerScope System consists of camera heads, endoscopes, video system, light source and other ancillary equipment.

Technological characteristics

The PeerScope GS video Gastroscope incorporates the following additional features compared to the predicate device:

Category	Subject Device: PeerScope GS Gastroscope	Predicate Device Gastrointestinal Videoscope GIF Type H180 (K100584)	Impact of the differences on device performance
Direction of Views	Front and left (side)	Front only	Both designs utilize standard front view.
Standard Field Of View [degrees]	160	140	Both designs utilize industry accepted standard for Field Of View.
Wide Field Of View [degrees]	210	Not included	The Presentation of the wide view option is a unique feature of the PeerScope System feature of the PeerScope System, which is not included EVIS EXERA II 180 System specifications.
Depth Of Field [mm]	3-100	2-100	Both designs utilize industry accepted standard for Depth Of Field.
Working Length [mm]	1050	1030	Both designs utilize industry accepted standard for Working Length
Distal tip Outer Diameter [mm]	10.5	9.8	Both designs utilize industry accepted standard for Distal tip Outer Diameter
Illumination Type	Integral LED illumination	Examination lamp	Both systems utilize accepted industry standard for illumination

Category	Subject Device: PeerScope GS Gastroscope	Predicate Device Gastrointestinal Videoscope GIF Type H180 (K100584)	Impact of the differences on device performance
Narrow band illumination	Not Included	Included	The narrow band illumination is a unique feature of The EVIS EXERA II 180 System, which is not included in the PeerScope System specifications.
Water Flow rate - lens irrigation	1.25 cc/ sec	0.9 cc/sec	Both systems utilize accepted industry standard for lens irrigation
Angulation Range [degrees]	Up 210, Down 120 Left 120, Right 120	Up 210, Down 90 Left 100, Right 100	Both systems utilize accepted industry standard for Angulation Range

Based on the results of verification, validation and performance testing, the impact of the above differences is insignificant in terms of the device safety and effectiveness for the device intended use.

Performance data

Bench data:
Risk analysis was conducted in accordance with ISO 14971. Design verification tests and their acceptance criteria were identified, preformed and met.

Software validation was carried out in accordance with FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005)".

Reprocessing validation was carried out in accordance with FDA Guidance Document "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Draft Guidance (May 2011)".

Device safety and performance were verified by EndoChoice Innovation Center Ltd. and accredited third party laboratories.

The following standards were used / relied upon for testing:

AAMI / ANSI ES 60601-1:2005/(R) 2012 and C1:2009/(R) 2012
AAMI / ANSI ES60601-1:2005/A1:2012
IEC 60601-1-2:2007
IEC 60601-2-18 Edition 3.0 2009-08
IEC 62304:2006
ISO 10993:2009 Part #1
ISO 10993:2009 Part #5
ISO 10993:2010 Part #10
ISO 10993:2007 Part #12
ISO 8600-1 Second edition 2005-05-01

ISO 8600-3 First edition 1997-07-01
ISO 8600-4 First edition 1997-07-01
ISO 8600-6 First edition 2005-03-15
ASTM E 1837- 96 (reapproved 2007)

Usability Data:
Device Usability was carried out by means of testing within a clinical environment in a US medical center by five experienced GI physicians.

The conclusions drawn from the bench and usability tests demonstrate that the device meets its specifications, and supports a determination that the device is at least as safe and effective for its intended use as the predicate device.

Substantial Equivalence

The above presented data demonstrate that:

a. The PeerScope System Model HG and the predicate device, EVIS EXERA II 180 System have the same intended use and indications for use in upper digestive tract.
b. The PeerScope System Model HG uses the same technologies used by the predicate PeerScope System Model H.
c. The PeerScope System Model HG does not raise different questions of safety and effectiveness.
d. The data provided collected by scientific acceptable methods, thus demonstrating equivalence and support the indications.

Conclusion: It is the opinion of EndoChoice Innovation Center Ltd. that the PeerScope system Model HG is substantially equivalent to the predicate devices, in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 10, 2013

EndoChoice, Inc.
% Tamar Fuerst
RA Manager
EndoChoice Innovation Center Ltd.
2 Hatochen Street, Business and Industrial Park (North), POB 3161
Caesarea
Israel 38900

Re: K131422
Trade/Device Name: PeerScope System (Model HG)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS
Dated: August 29, 2013
Received: September 9, 2013

Dear Tamar Fuerst,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Glenn B. Bell -S

Acting for:
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131422

Device Name: PeerScope System (Model HG)

Indications for Use:
The PeerScope System is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The PeerScope System is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).
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Prescription Use ____X____AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Glenn B. Bell -S